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2.01: General Provisions

- (1) <u>Scope</u>. 114.5 CMR 2.00 governs the disclosure of hospital case mix and charge data submitted by hospitals to the Division of Health Care Finance and Policy pursuant to 114.1 CMR 17.00.
- (2) <u>Purpose</u>. 114.5 CMR 2.00 is adopted to safeguard the privacy rights of case mix data subjects while permitting limited access to such data where such access serves the public interest. Uses that serve the public interest include, but are not limited to: health cost and utilization analysis to formulate public policy; financial studies and analysis of hospital payment systems; utilization review studies; investigations of fraud and abuse; hospital merger analyses; health planning and resource allocation studies; epidemiological studies, including the identification of morbidity and mortality patterns, and studies of prevalence and incidence of diseases; and research studies and investigation of other health care issues.
- (3) Effective Date. 114.5 CMR 2.00 shall be effective when published.
- (4) <u>Authority</u>. 114.5 CMR 2.00 is adopted pursuant to M.G.L. c.118G and M.G.L. c. 66A, the Fair Information Practices Act.

2:02: Definitions

As used in 114.5 CMR 2.00, the following words shall have the following meanings: <u>CMS</u>. The federal Centers for Medicare and Medicaid Services, formerly the Health Care Financing Administration, or HCFA.

Case Mix Data. Case specific, diagnostic discharge data which describe socio-demographic characteristics of the patient, the medical reason for the admission, treatment and services provided to the patient, and the duration and status of the patient's stay in the hospital. Case mix data includes, but is not limited to, the inpatient data elements specified in 114.1 CMR 17.04 and 114.1 CMR 17.05, outpatient observation stay data elements specified in 114.1 CMR 17.08, emergency department data elements specified in 114.1 CMR 17.15, and associated administrative bulletins. Case mix data do not include patient name or social security number. Case mix data include a unique health identification number (UHIN) encrypted by the Division from the patient's social security number and a unique physician number (UPN) also encrypted by the Division from the physician Board of Registration in Medicine License Number.

<u>Charge Data</u>. The full, undiscounted total and service specific charges billed by the hospital to the general public as defined in M.G.L. c.118G. Charge data shall include, but not be limited to, the data elements specified in 114.1 CMR 17.04, 114.1 CMR 17.08, and 114.1 CMR 17.15.

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<u>Division</u>. The Division of Health Care Finance and Policy established under M.G.L. c.118G.

<u>Deniable Data Elements</u>. Those data elements which either solely or in combination with other data elements jeopardize patient privacy and which will not be disclosed unless the Division determines that an applicant fulfills the requirements imposed by 114.5 CMR 2.03. Deniable data elements include medical record number, mother's medical record number, billing number, the Medicaid Recipient Identification Number (Claim Certificate Number), the UHIN, date of admission (registration or begin date), date of discharge (end date), date of birth, date(s) of surgery, and the UPN. Additional deniable ED data elements include stated reason for visit and ambulance run sheet number.

<u>Level I Data</u>. Case mix data which includes all data elements with the exception of deniable data elements. Level I data may include, but is not limited to, the following summative data fields as determined by the Division: month and year of encounter, month and year of departure, length of inpatient stay, day(s) in hospital when surgery occurred; age of patient at one year intervals for patients one year or older; and age of patient at one week intervals (or other standard intervals) for patients less than one year old.

Level II Data. Case mix data which include Level I Data plus the UPN.

<u>Level III Data</u>. Case mix data which include Level I Data plus the UHIN, the mother's UHIN, an admission sequence number for each UHIN record, and may include days between stays for each UHIN record.

<u>Level IV Data</u>. Case mix data which includes Level I Data plus the UPN, the UHIN, the mother's UHIN, an admission sequence number for each UHIN record, and may include days between stays for each UHIN record, and stated reason for visit. Level IV for ED data also includes reason for visit.

<u>Level V Data</u>. Case mix data which include Level IV Data plus the date of admission (registration or begin date), date of discharge (end date) and date(s) of surgery.

<u>Level VI Data</u>. Case Mix data which include all the deniable data elements identified in 114.5 CMR 2.02 except the Medicaid Recipient Identification Number.

<u>UHIN</u>. A unique health identification number encrypted by the Division from the patient's social security number.

<u>UPN</u>. A unique physician number encrypted by the Division from the physician Board of Registration in Medicine License Number.

2.03: Procedures

(1) General Requirements. All individuals and agencies outside of the Division that request access to or use of case mix data shall submit a written application. The applicant must demonstrate a need for the data and for each deniable data element requested. The Division will release only those deniable data elements which it determines to be necessary to accomplish the applicant's intended use.

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- (a) All applicants for the data shall specify:
 - 1. the level of data requested.
 - 2. the purpose for which the data is being requested.
 - 3. a detailed project description or other specific use intended for the data:
 - 4. the reason why the applicant needs any requested deniable data elements to accomplish its stated purpose;
 - 5. the applicant's qualifications to perform such research or accomplish the intended use; and
 - 6. the security and privacy measures to be taken in order to safeguard patient privacy and to prevent unauthorized access to or use of such data.
 - (b) All applicants for the data shall make assurances that:
 - 1. data will be used only for the purpose stated in the request;
 - 2. no attempt will be made to use any data supplied to learn the identity of specific patients;
 - 3. no data containing deniable data elements organized by individual record of discharge will be released to any other person or entity except as specified in 2.03(1)(c); and
 - 4. the applicant can ensure that any recipient of data or agent which process data on behalf of the applicant will be bound by the assurances contained in 2.03(1).
- (c) Approved applicants holding the data:
 - 1. may release to a hospital the hospital's own case mix data for the sole purpose of verifying the accuracy of the hospital's data; and an applicant may release a report or transfer or exchange data which contains only non-deniable data elements, provided the recipient makes the assurances provided in paragraph (b) above.
 - 2. may release a report or transfer or exchange data which contains only Level II data elements provided that no data organized by individual record of discharge with a Unique Physician Number will be released for combinations of six records or fewer.
 - 3. may release a summary study which aggregates multiple records organized by UHIN and which does not disclose the actual UHIN or any deniable data elements.
 - 4. must, prior to releasing a report to another person or entity for Level III, Level IV, Level V or Level VI data, submit to the Division either a copy of the report or a proposal for a standard report format, including summary studies which aggregate multiple records organized by UHIN, so that the Division can determine whether the privacy rights of any data subject would be violated by such release.

(2) Application Approval Criteria.

- (a) The Division will approve an application if it determines that:
 - 1. the purpose for which the data is requested is in the public interest as defined in 114.5 CMR 2.01(2);

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- 2. the applicant has demonstrated it is qualified to undertake the study or accomplish the intended use;
- 3. the applicant requires such data in order to undertake the study or accomplish the intended use;
- 4. the applicant can insure that patient privacy will be protected; and
- 5. the applicant can safeguard against unauthorized use; and
- 6. the applicant can insure that any recipient or agent which process data on behalf of the applicant will be bound by the assurances contained in 2:03 (1).
- (b) If the Division determines that the needs of an applicant can be satisfied by releasing fewer deniable data elements than the number of deniable elements contained in the requested level, the Division will authorize access to the level containing the fewest number of deniable data elements.
- (3) The Division shall notify each applicant of its decision within 30 days of its receipt of a completed application. If the application is incomplete or if the Division determines that supplemental information is needed to make its decision, the Division may require such supplemental information and shall notify the applicant of its decision within 30 days of its receipt of such information.
- (4) The Division may release case mix data to:
 - (a) organizations under contract to the Division to undertake studies;
 - (b) other government agencies whose applications meet the criteria set forth in 114.5 CMR 2.03; and
 - (c) if the criteria set forth in 114.5 CMR 2.03 are met, the Division will not limit the right of the following entities to receive case mix data to the extent permitted by applicable laws and regulations:
 - 1. the Centers for Medicare and Medicaid Services;
 - 2. the Division of Medical Assistance may receive case mix data pertaining to Medicaid patients and such case mix data may also include the Medicaid Recipient Identification Number; and
 - 3. the Department of Public Health may receive data in order to perform studies concerning public health.
- (5) The Division shall charge a fee to all persons and organizations requesting case mix and charge data. The fee may reflect the total cost of systems analysis, program development, and computer production costs incurred in producing the requested data, and postage. Applicants may also be required to furnish their own tape or other appropriate medium to the Division for processing. The fee may be waived in the following instances:
 - (a) requests by CMS or an agency of the Commonwealth;
 - (b) requests by researchers that can demonstrate that imposition of a fee would constitute a hardship.

2.04: Administrative Information Bulletins

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The Division may, from time to time, issue administrative information bulletins to clarify its policy upon and understanding of substantive provisions of 114.5 CMR 2.00. In addition, the Division may issue administrative information bulletins which specify the information and documentation necessary to implement 114.5 CMR 2.00.

2.05: Sanctions

If an approved applicant fails to comply with any of the requirements and conditions for receiving case mix and charge data in 114.5 CMR 2.00, the Division may:

- (1) deny access to case mix or charge data in the future;
- (2) terminate current access to case mix or charge data; or
- (3) demand and secure the return of all case mix and charge data.

Violations of 114.5 CMR 2.00 may also subject the violator to applicable statutory sanctions.

REGULATORY AUTHORITY

114.5 CMR 2.00: M.G.L. c.118G and M.G.L. c. 66A.